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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,514	02/11/2004	Kerry Zang	073275.0163	5263
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BAKER BOTTS L.L.P. 2001 ROSS AVENUE SUITE 600 DALLAS, TX 75201-2980			EXAMINER MILLER, CHERYL L	
			ART UNIT 3738	PAPER NUMBER
			NOTIFICATION DATE 01/28/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/777,514

Applicant(s)

ZANG ET AL.

Examiner

Cheryl Miller

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-44, 46-57, 62, 63 and 65-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-44, 46-57, 62, 63, 65-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/11/04 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 31, 2007 has been entered.

Response to Arguments

Applicant's arguments with respect to claims 40-69 have been considered but are moot in view of the new ground(s) of rejection.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Although the specification recites the thread height to be approximately 0.032 inches, there is no antecedent basis in the specification for a "substantially constant" thread height as claimed in claims 40, 55, 67, and 70. The same is true for the thread pitch. Although the specification recites a single value for the pitch, there is no antecedent basis for a "substantially constant pitch" as claimed in claims 46 and 48.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "constant thread height" must be

shown or the feature(s) canceled from the claim(s). No new matter should be entered. Figures 1a-1b currently appear to have a tapered thread height.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 46, 48, 49, 65 and 70 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 46, 48, 49, and 65 each recite the term "majority". Support for the term "majority" was not found in the specification. The applicant relies on the drawings for support for "majority" however this is not found persuasive by the examiner since only one embodiment (one measurement or fraction) is shown in the figures 1a-1c. Although the fraction shown may be a "majority", majority is broader in coverage than the one embodiment shown. Majority is defined as more than half and encompasses 51-100 percent and the applicant has not shown the entire range, thus majority is broader than the applicant has support for.

Referring to claim 70, the embodiment elected in figures 1a-1c show only a thread that extends the entire length. The applicant does not have support for the threads traversing only "a portion" of the length, at least not in the elected embodiment.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 40, 41, 50, 52, 53, 55, 56, 62, and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Bailey et al. (US 5,607,304, cited previously). Bailey discloses a medical implant (16; fig.1, 2) comprising a body (shaft portion of 16) *adapted* for implantation into the sinus tarsi (is capable of placement at such a location), the body (shaft of 16) comprising a first end (top of shaft where threads begin), a second end (bottom of shaft where threads end) and at least one continuous and uninterrupted thread (22) including a crest with a flat surface (37) and constant

thread height (appears constant in figures; col.3, lines 2-7), the thread (22) helically traversing the length of an exterior surface of the body (threads span entire shaft portion of 16), the length spanning from the first to second end, a recessed engagement (at 23) in the first end and wherein a circumference of the exterior surface of the body tapers from the first end to the second end (see fig.2). Bailey has shown a body (shaft of 16) that is generally conical and appears to taper uniformly (see fig.2).

Claims 40, 41, 44, 47, 50, 52-56, 62, 63, 66, and 70 are rejected under 35 U.S.C. 102(b) as being anticipated by Persoon's (US 5,683,460). Persoon's discloses a medical implant (101; fig.2) comprising a body (102) *adapted* for implantation into the sinus tarsi (is capable of placement at such a location), the body (102) comprising a first end (108), a second end (104) and at least one continuous and uninterrupted thread (105) including a crest with a flat surface (see fig.2; col.3, lines 23-25) and constant thread height (appears constant in figs), the thread helically traversing the length of an exterior surface of the body (thread traverses entire length), the length spanning from the first to second end, a recessed engagement (recess or hollow; col.4, lines 2-3, 5-7; col.2, lines 7-8) in the first end and wherein a circumference of the exterior surface of the body tapers from the first end to the second end (see fig.2). Persoon's has shown a body (102) that is generally conical and appears to taper uniformly (see fig.2). Persoon's discloses a flat face on the first end (108) with a recess (col.4, lines 5-7) and flat face on the second end (104a; see fig.2) surrounding bore (hollow; col.4, lines 2-3; col.2, lines 7-8).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 43, 46, 48, 49, 51, and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey et al. (US 5,607,304, cited previously). Bailey discloses a medical implant and method of forming the implant substantially as claimed (see above) having what appears to be constant repeated threads (thus constant pitch and height). Bailey is silent however to mention specific dimensions of the threads (angle, pitch, height, root width). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the dimensions claimed, since wherein the general conditions are disclosed in the prior art (threads having a height, pitch, width, etc) it is not inventive to discover the optimum or workable ranges (dimensions claimed). *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Claims 40, 46, 48-50, 52, 53, 55, 65, and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crombie (US 5,961,524, cited in IDS). Crombie discloses a medical implant (10) comprising a body (entire screw 10) *adapted* for implantation into the sinus tarsi (is capable of placement at such a location), the body comprising a first end (top of screw head), a second end (bottom of screw) and at least one continuous and uninterrupted thread (20) including a crest (22) having a constant thread height (col.4, lines 20-23), the thread (20) helically traversing the length of an exterior surface of the body (thread does traverse some of the length; it is noted to applicant that the thread is not required to traverse the *entire* length of the body), the length spanning from the first to second end (the length does span this distance-threads are not required to span this distance), a recessed engagement (24) in the first end (top of screw head) and

wherein a circumference of the exterior surface of the body tapers from the first end to the second end (see figs). Crombie discloses the medical implant substantially as claimed, however discloses a rounded crest instead of a flat crest as claimed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a flat crest since although Crombie discloses a rounded crest (22), Crombie also discloses the optional use of other shaped crests (col.4, lines 30-35). A flat crest is known in the screw art to be a common crest shape (see as evidence, Simon et al. US 5,951,560) and would have been an obvious substitution of change of shape from the rounded crest shape. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

Claims 42 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Persoon's (US 5,683,460) in view of Simon et al. (US 5,951,560, cited previously). Persoon's discloses a medical implant and method of forming the medical implant substantially as claimed (see above). Persoon's discloses a body (102) having a recessed engagement and a bore used for implantation and guiding into bone (col.4, lines 2-8), however does not show details of the recess and bore (the claimed hexagonal, cylindrical and countersunk is not shown). Simon teaches in the same field of medical implants (specifically bone screws similar to Persoon's), the use of a hexagonal, cylindrical, and countersunk recess (seen in figs.2, 3), for the purpose of guiding and implanting the medical implant into bone just as Persoon's. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Simon's specific recess structure (hexagonal, cylindrical, and countersunk) with Persoon's recitation of a recessed engagement since it would be common sense to use a known engagement in the art (Simon's) with the screw of Persoon's which discloses use of engagement structures.

Claims 67-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zdeblick et al. (US 2004/0097928 A1) in view of Kohrs et al. (US 5,897,593). Zdeblick discloses a medical device (10; fig.2-8) and method of implanting the device into the sinus tarsi (P0066) the device comprising a body (11) having a first end (13), second end (12), at least one continuous and uninterrupted thread (19; traverses a portion of the length, near end 12) including a crest with a flat surface (see fig.2, 8; truncated, P0036) having a constant thread height (thread 19 has a constant height; 1 mm, P0036) and helically traversing the length (Zdeblick's thread 19 traverses the length-it is noted that the claims do not require the thread to transverse the entire length), the length extending from the first end to the second end (see figs), a recessed engagement in the first end (hex recess, P0040), a bore extending through the body (15), and the body tapering from the first to second end (see fig.2, 8). Zdeblick discloses the device substantially as claimed, however has not shown the detail of the hex recess engagement, and it is unclear whether the bore connects with the recess or not, since it is not illustrated in the figures. Kohrs teaches in the same field of medical implants as Zdeblick, a body having a recessed engagement (40) wherein the bore (hollow) extends from the recessed engagement to the second end (see fig.5; this is not clear in the Zdeblick patent whether the structures are connected). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Zdeblick's implant having a recited bore and recess (details not shown) with Kohr's teaching of an example of how recessed engagements and bores may be oriented (bore extending from the engagement to the second end) since it would provide predictable result and be common sense to use Kohr's

particular engagement bore orientation with Zdeblick's device since Zdeblick has disclosed use of such features.

Conclusion


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cheryl Miller/


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